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| 10/645,554      | 08/22/2003  | Yoshinao Nagashima   | 240945US0DIV        | 8690             |

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/645,554

Applicant(s)

NAGASHIMA ET AL.

Examiner

Lakshmi S Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8-22-03; 11-24-03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-14 and 20 have been canceled by preliminary amendment. Claims 15-19 are pending prosecution.

Receipt of IDS dated 11-24-03 and 8-22-03 is acknowledged.

Instant claim 15 is directed to a composition consisting essentially of a sesquiterpene alcohol in air, wherein said sesquiterpene alcohol is present at a concentration of from 0.01 to 100 ppb, and further wherein said sesquiterpene alcohol has an odor below a detectable threshold, a boiling point of at least 2500C and is in a vaporizable state.

Claim 16 is a lotion consisting essentially of an sesquiterpene alcohol, present at a concentration of from 0.01 to 0.05 weight percent, has an odor below a detectable threshold and has a boiling point of at least 250C.

Claim 17 is an emulsion consisting essentially of a sesquiterpene alcohol, present at a concentration of 0.01 to 7.50 weight percent, has an odor below a detectable threshold and has a boiling point of at least 250 C, and a carrier.

Claim 18 is a pharmaceutical composition comprising a pharmaceutically acceptable carrier or excipient and composition, said composition comprising a sesquiterpene alcohol, wherein said composition has an odor below a detectable threshold and said sesquiterpene alcohol has a boiling point of at least 250 C.

Claim 19 is a pharmaceutical composition claimed in claim 18, further comprising an emulsifier, oil, glycol, sugar, starch or mixture thereof.

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***Claim Rejections - 35 USC § 112***

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim recites sesquiterpene alcohol in air, which is vague and indefinite. Instant claim is directed to a composition, whereas the limitation recited is “in air”. It is unclear to the examiner as to how a component in a composition can be measured by its presence in air rather than in the composition. Further, examiner assumes that the amount specified as parts per billion is the concentration of the alcohol claimed, in air. A clarification and correction is requested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 61129140 (JP ‘140).

JP ‘140 discloses a pharmaceutical composition having sesquiterpene alcohol composed mainly of alpha-bisabolol (abstract). JP ‘140 does not explicitly recite the claimed boiling point or the threshold for detecting the odor or if it is in a vaporizable state. However, it is examiner’s position that the claimed boiling point, volatility and the odor threshold is inherent to the

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sesquiterpene alcohol of JP '140, because a compound inherently possess its characteristics which are inseparable form the compound.

Claims 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10036247 (JP 247).

JP '247 discloses a suppressant for melanogenesis comprising guaiol, a sesquiterpene alcohol in an amount of 0.01% to 10% by weight (abstract). JP '247 does not explicitly recite the claimed boiling point or the threshold for detecting the odor or if it is in a vaporizable state. However, it is examiner's position that the claimed boiling point, volatility and the odor threshold is inherent to the sesquiterpene alcohol of JP '247, because a compound inherently possess its characteristics which are inseparable form the compound.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10036247 (JP '247).

JP '247 discussed above teaches a medicinal composition comprising guaiol in an amount of 0.10% to 10% by weight. While JP '247 does not specifically exemplify the claimed lotion, cream or emulsion contain the same (abstract), JP '247 suggests preparing the composition in the form of a cream, lotion, oily gel, pack etc. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a composition comprising

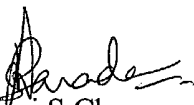
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guaiol in the form of a cream, lotion or emulsion by adding the required solvents or emulsifiers and because JP '247 suggests preparing the above cosmetic or pharmaceutical forms containing guaiol as an active ingredient and use for the treatment of skin for the suppression of melanogenesis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
December 10, 2004